

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of Dorema Ammoniacum Cream on the prevention of peripheral intravenous catheter-related phlebitis In patients admitted to surgery departments

Protocol summary

Study aim

Determining the effect of Dorema Ammoniacum cream on the prevention of phlebitis caused by peripheral venous catheters in patients admitted to the surgical wards of Shariati Hospital

Design

Clinical trial has two groups of intervention (Dorema Ammoniacum cream) and control (cream base). Assignment of samples to two groups with a random permutation block design will be two treatments with quadruple blocks. The study is three-way blind and the sample size is 55 people in each group.

Settings and conduct

This study is a three-blind randomized clinical trial in two groups. The patient, the researcher, the research assistant and the statistical analyzer have no knowledge of how the cans are named and the contents inside. After analyzing the data, the cream manufacturer will be asked about the contents of the cans. The research will be performed in the surgical ward of Shariati Hospital in Tehran. The study population was all patients admitted to the surgical ward and the research sample was all patients with peripheral venous catheter and at risk of phlebitis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalization in the surgical ward The patient is alert and able to understand and describe pain Necessary desire and cooperation from the patient The age of the samples is between 18 and 60 years Exclusion criteria: Grade 2, 3 and 4 phlebitis Fever

Intervention groups

There are two intervention groups, the experimental group that receives the Dorema Ammoniacum cream and the control group that receives the cream base.

Main outcome variables

Degree of phlebitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201119049441N1**

Registration date: **2021-01-18, 1399/10/29**

Registration timing: **prospective**

Last update: **2021-01-18, 1399/10/29**

Update count: **0**

Registration date

2021-01-18, 1399/10/29

Registrant information

Name

zohreh hemmatpor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6591 6096

Email address

z.hemmatpor@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-03, 1399/11/15

Expected recruitment end date

2021-06-05, 1400/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Dorema Ammoniacum Cream on the prevention of peripheral intravenous catheter-related phlebitis in patients admitted to surgery departments

Public title

Effect of Dorema Ammoniacum Cream on the prevention of peripheral intravenous catheter-related phlebitis in patients admitted to surgery departments

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Hospitalization in the surgical ward
Implantation of a peripheral venous catheter in the upper limb, in a place without signs of phlebitis
The patient is alert and able to understand and describe pain
Necessary desire and cooperation from the patient
The age of the samples is between 18 and 60 years
No diabetes
No skin disorders and eczema
Lack of sensitivity to peripheral venous catheter adhesive
Lack of chemotherapy
No acute infectious diseases

Exclusion criteria:

Grade 2, 3 and 4 phlebitis
Fever

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

After adapting the patient's condition to the inclusion criteria, patients are randomly assigned to one of the two experimental or control groups. Thus, the letter A is considered for the intervention group and the letter B is considered for the control group. Then we write all the permutation combinations of the letters A, A, B and B, which are 6 different combinations, on 6 cards as follows: AAB, AB, AB, BA, BA, BA, then we randomly select a digit from 1 to 6 (With the help of a table of random numbers or we ask patient number one to choose a card at random). For example, if the number 2 is selected, it means that the first person in the intervention group will be the next two people in the control group and the fourth person in the intervention group, and we will continue this operation until the sample size reaches the quorum.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The blinding of the study is that the Dorema Ammoniacum cream and placebo made by the research team are both completely similar in terms of color, odor, consistency and cans used, and the cans are named A and B by the cream maker. The patient, the researcher and the assistant researcher and the statistical analyzer have no information about how to name the cans and the contents inside them, and finally, after analyzing the data, the manufacturer of the cream will be asked about the contents of the cans.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the School of Nursing and Midwifery, Tehran University of Medical Sciences

Street address

Tehran, Tohid Square, Dr. Mirkhani St. (Eastern Nusrat), School of Nursing and Midwifery

City

tehran

Province

Tehran

Postal code

1419733171

Approval date

2020-10-20, 1399/07/29

Ethics committee reference number

IR.TUMS.FNM.REC.1399.116

Health conditions studied

1

Description of health condition studied

Phlebitis

ICD-10 code

180.8

ICD-10 code description

Phlebitis and thrombophlebitis of other sites

Primary outcomes

1

Description

Degree of phlebitis

Timepoint

Determining the degree of phlebitis at 12, 24, 36, 48, 60 and 72 hours after implantation of peripheral venous

catheter and application of Dorema Ammoniacum cream.

Method of measurement

The VIP Infusion Visual Scale Checklist for Phlebitis was developed to assess the position around the peripheral venous catheter for phlebitis and was rated from 0 (no phlebitis) to 5 (advanced thrombophlebitis). Evidence of phlebitis that can be observed and examined for scoring has been stated and action that is appropriate for that stage of phlebitis has been stated.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, Dorema Ammoniacum cream is used. To prepare Dorema Ammoniacum cream, 100 grams of Dorema Ammoniacum resin oleogum is weighed and ground. 1 liter of 70 degree alcohol is added to it. Clears after 48 hours. Add another liter of alcohol and strain it again after 48 hours. The filtered solution is concentrated by rotary rotation. The concentrated solution is placed in a vacuum oven to form a powder. 5 g of the powder with 20 cc of distilled water is placed in an ultrasonic bath for 15 minutes to obtain a uniform liquid. A uniform liquid is added to 100 g of the base cream and it is beaten evenly with an electric mixer to obtain a uniform cream. It is then packed in 50 g containers. 70% alcohol is used only for extraction and after drying the extract, nothing of alcohol remains in the extract. Before using the cream, a skin allergy test is performed, in which some cream is rubbed on the patient's arm and after For 20 minutes the position is examined for redness, rash and other allergic reactions, and if there is no reaction, the drug will be tested on the patient. The product is standardized by spectrophotometric method based on the amount of spirochete compounds of terpenoic chromium acid 2-4-dione. Ash essential oil is also isolated and its compounds are identified by GC-MS. According to the European Pharmacopoeia, skin-mucosal products do not need to be sterilized.

Category

Prevention

2

Description

Control group: The base cream is prepared by Farabi company and consists of Vaseline, glycerin, monostearate, beeswax, lanolin, stearic acid, alcohol, distilled water, triethanolamine. To prepare the placebo, the base cream is in 50 containers. It is warmly packaged. Before using the cream, a skin allergy test is performed, in which some cream is rubbed on the patient's arm, and after 20 minutes, the position for redness, rash and other allergic reactions is examined. If there is no reaction, the drug will be tested on the patient.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Hemmatpor Zohreh

Street address

Shariati Hospital., Jalal Al-Ahmad Intersection., North Kargar St., Tehran in front of the Faculty of Economics,.

City

Tehran

Province

Tehran

Postal code

1411713135

Phone

+98 21 8490 1000

Email

shariatihosp@tums.ac.ir

Web page address

<http://shariati.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Sahraeian, Mohammad Ali

Street address

Imam Khomeini Ave., Hasan Abad Sq., Sina Hospital
Tehran - Iran

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6670 6142

Email

msahrai@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Postal code

3354462338

Phone

+98 21 6591 6096

Email

z.hemmatpor@gmail.com

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hemmatpor, Zohreh

Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 7.2, First Floor, Unit 2, West 1st Arghavan St.,
Doniamali Blvd., 1st phase of andishe., Shahriar,
Tehran.

City

Tehran

Province

Tehran

Postal code

3354462338

Phone

+98 21 6591 6096

Email

z.hemmatpor@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hemmatpor, Zohreh

Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

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No. 7.2, First Floor, Unit 2, West 1st Arghavan St.,
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Tehran.

City

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Province

Tehran

Postal code

3354462338

Phone

+98 21 6591 6096

Email

z.hemmatpor@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Hemmatpor, Zohreh

Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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Doniamali Blvd., 1st phase of andishe., Shahriar,
Tehran.

City

Tehran

Province

Tehran

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available